IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	)	C.A. No.: 04-940-JJF **-REDACTED-** **PUBLIC VERSION**

THE PROCTER & GAMBLE COMPANY'S MOTION IN LIMINE TO STRIKE THE "EXPERT REPORT OF JESSE DAVID, PH.D."

Pursuant to Federal Rule of Civil Procedure 37(c)(1) and Federal Rules of Evidence 702, 703 and 704, plaintiff The Procter & Gamble Company ("P&G") hereby moves to strike the untimely filed and inadmissible "Expert Report of Jesse David, Ph.D." ("David Report") submitted by defendant Teva Pharmaceuticals USA, Inc. ("Teva") on April 12, 2006 -- four weeks after the final deadline for all rebuttal expert reports -- and to preclude Dr. David or any other Teva expert from testifying about the topics addressed in the David Report at any deposition, hearing, or trial in this matter.

I. BACKGROUND

Pursuant to the Court's initial Rule 16 Scheduling Order in this case, the parties were permitted two rounds of expert report submissions -- initial expert reports on issues on which a party bore the burden of proof, which were due on November 14, 2005, and rebuttal reports, which were due on December 19, 2005. (*See* D.I. 28, Rule 16 Scheduling Order, dated May 31, 2005). On October 31, 2005, at the request of the parties, the Court amended the Scheduling Order in this case to require the parties to submit initial expert reports by December 7, 2005 and to submit rebuttal expert reports by January 20, 2005. (*See* D.I. 60, Stipulated Amended

Scheduling Order, dated Oct. 31, 2005). By agreement of the parties, the expert report schedule was further amended so as to permit the submission of initial expert reports on January 26, 2006.

Because Teva stipulated to infringement of the patent-in-suit, U.S. Patent No. 5,583,122 (the "'122 patent"), and because there is no damages claim in this ANDA-related action, P&G did not bear the initial burden on any issue for purposes of the January 26, 2006 deadline. As a result, because Teva bears the burden of proof on its only defense -- invalidity of the asserted claims of the '122 patent -- only Teva was required to submit a report on the initial expert report deadline.

On January 26, 2006, Teva submitted the "Expert Report of George R. Lenz, Ph.D." ("Lenz Report"). Dr. Lenz purported to set forth several reasons why the asserted claims of the '122 patent should be held invalid, including that those claims were anticipated by the prior art and/or rendered obvious. As part of his analysis, Dr. Lenz addressed several of the secondary considerations factors that P&G had identified in response to interrogatories as rebutting a finding of obviousness, including unexpected results and commercial success. With respect to commercial success, Dr. Lenz's opinion, in relevant part, reads as follows:

REDACTED

REDACTED

On February 24, 2006, P&G filed two reports in rebuttal to the Lenz Report, including the "Expert Report of Dr. Daniel C. Smith" ("Smith Report"), which presented facts and expert analysis to rebut Dr. Lenz's opinion that

REDACTED On March 10, 2006, again by agreement of the parties, P&G submitted four additional rebuttal expert reports, each of which addressed the technical aspects of Dr. Lenz's opinion.[1] Teva submitted no further reports at that time.

However, on April 12, 2006, four weeks after the agreed-upon deadline for the submission of rebuttal reports and without seeking or obtaining the assent of P&G, Teva submitted a second expert report, (the David Report,) which purported to rebut the rebuttal expert report of Dr. Smith on the issue of commercial success.[2] **REDACTED**

However, his report is bereft of any economic analysis or any other analysis related to Dr. David's knowledge, skill, experience, training or education. Instead, the David Report is a legal memorandum in the guise of an expert disclosure; it offers no scientific, technical or specialized knowledge to assist the trier of fact. Rather, it purports to analyze the legal relevance of commercial success in patent litigation. Indeed, in spite of its submission as a

[1] P&G requested this further extension, to which Teva assented, because, in his expert report, Dr. Lenz had identified and relied upon approximately four prior art references that had not previously been identified by Teva in interrogatory responses or produced in response to P&G's document requests seeking the disclosure of prior art references upon with Teva intended to rely. As a result, P&G's technical experts required additional time to review and analyze these references in order to fully address them in their reports.

REDACTED

supposed rebuttal to the Smith Report, the David Report does not rebut a single fact or opinion set forth in the Smith Report.

II. ARGUMENT

A. The David Report is Inadmissible

The David Report is inadmissible under the Rules of Evidence because it consists entirely of improper legal opinions regarding the evidentiary weight that should be accorded evidence of commercial success, rather than expert rebuttal testimony addressing the marketing and commercial success issues discussed in the Smith Report. Such legal conclusions are not the proper subject of expert testimony, and therefore should be precluded.

Dr. David does not cite a *single* document produced in this litigation, other than a few patents, does not challenge *any* of the facts or opinions set forth in the Smith Report, and does not offer *any* economic analysis of his own. Instead, he simply makes numerous improper, overbroad, and conclusory statements about the law of commercial success, and in particular, the Federal Circuit's decision in *Merck & Co., Inc. v. Teva Pharms. USA*, 395 F.3d 1364 (Fed. Cir. 2005). **REDACTED** Dr. David offers the "opinion" that, based on a recitation of case law from several jurisdictions:

REDACTED

This legal conclusion based on case law interpretation can in no way "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. As such, the David Report is inadmissible. *See, e.g., Watkins v. New Castle County*, 374 F. Supp. 2d 379, 393 (D. Del. 2005) (precluding testimony of an expert witness as to whether defendants' conduct satisfied the legal standard at issue because Federal Rules of Evidence do not permit expert testimony as to legal conclusions which are in the Court's decision making power); *Lynch v. J.P. Stevens & Co.*, 758 F. Supp. 976,

1014 (D.N.J.1991) ("Legal conclusions are not within the ambit of expert testimony permitted under Rule 703."); *see also, e.g., Williams v. Wal-Mart Stores, Inc.*, 922 F.2d 1357, 1360 (8th Cir.1990) (although expert witnesses are permitted to offer an opinion on the ultimate issue in the case pursuant to Fed. R. Evid. 704(a), court may exclude expert testimony if it is nothing more than legal conclusions).

Even assuming *arguendo* that the David Report offered admissible opinions, Dr. David does not and cannot qualify as an expert to provide the legal opinions set forth in his report. To qualify as an expert under Federal Rule of Evidence 702, a witness must first establish his expertise by demonstrating "knowledge, skill, experience, training, or education" in the relevant subject area. Fed. R. Evid. 702. Dr. David does not have a law degree, and he is not licensed to practice before the U.S. Patent and Trademark Office. **REDACTED** He is neither a law professor nor an expert in legal precedent. Moreover, Dr. David has had no experience, training, or education in the relevant fields of study and therefore cannot possibly possess the knowledge necessary to deliver credible expert testimony in this lawsuit on the topics addressed in his report. Instead, Dr. David purports to be a qualified expert on the topic of economics in intellectual property. **REDACTED** Dr. David's academic and professional background in no sense qualifies him to testify as to the proper evidentiary weight to afford secondary considerations of non-obviousness in a patent infringement lawsuit, much less to analyze or draw conclusions about legal arguments set forth in case law. Nor is Dr. David qualified to opine on who "qualifies as

REDACTED Yet, these are precisely the subjects addressed in Dr. David's report.

In short, Teva attempts to use Dr. David as an improper proxy to deliver legal arguments to the Court about the obviousness of the patent-in-suit. This thinly veiled effort is inappropriate under the Rules of Evidence and the Court should exclude Dr. David's report and testimony for this reason alone. *See Watkins*, 374 F. Supp. 2d at 393; *Haberern v. Kaupp Vascular Surgeons Ltd. Defined Benefit Plan and Trust Agreement*, 812 F. Supp. 1376, 1378 (E.D. Pa.1992) ("While the Federal Rules of Evidence permit helpful expert opinion that embraces an ultimate factual issue to be decided, they do not permit opinion on a question of law.").

B. The David Report Is Untimely

Apart from the improper and inadmissible legal opinions offered by Dr. David in his report, Teva submitted the report nearly two months after the deadline set forth in the Court's Scheduling Order. Under these circumstances, the Court should strike the David Report. *See Trilogy Comm. Inc. v. Times Fiber Comm., Inc.*, 109 F.3d 739, 745 (Fed. Cir. 1997) (upholding the exclusion of untimely "rebuttal" expert report containing new opinions in contravention of the court's scheduling order).

Teva can provide no justification for its failure to submit the David Report pursuant to the agreed-upon deadline for submitting initial expert reports. Teva has stated that P&G bears the burden of proof on the issue of commercial success and the David Report is a rebuttal to P&G's expert report on this issue. This argument fails for several reasons.

First, the issue of commercial success simply does not arise until Teva has made out a *prima facie* case of obviousness. *See, e.g., Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291-92 (Fed. Cir. 1985) (presumption of patent validity requires a patent challenger to bear the initial burden of demonstrating a prima facie case of obviousness, and only after a prima facie case is established does the burden then shift to the patentee to come forward

with rebuttal evidence of non-obviousness, including commercial success). Accordingly, P&G did not have an obligation to address commercial success until *after* Teva had set forth its position on obviousness in the Lenz Report. Tellingly, in negotiating the amended expert report schedule, P&G *informed* Teva that it was planning to submit a rebuttal report on the issue of commercial success, and Teva did not complain then, or when it received the Smith Report, that such a report was untimely, evidencing its recognition that P&G followed the proper procedure in submitting the Smith Report as a rebuttal to the Lenz Report.

Second, Teva was aware that P&G planned to assert commercial success as a secondary consideration supporting a finding of non-obviousness based on P&G's responses to interrogatories.

REDACTED

As a result, Teva's only initial expert report, the Lenz Report, addressed the issue of commercial success. Therefore, Teva could have, and should have, presented the ostensible "opinions" in the David Report at the same time as it submitted the Lenz Report, instead of waiting more than *two months* after the agreed-upon deadline for initial expert reports to do so. Alternatively, if Teva intended to engage in yet a third round of expert reports, it should have requested permission from the Court to do so either at the outset of the case when the parties submitted the proposed Rule 16 Scheduling Order, or when it became aware that P&G intended to present evidence of commercial success to rebut a finding of obviousness, instead of unilaterally extending expert discovery by submitting the David Report on a date of its own choosing.

Third, although guised as a rebuttal to P&G's Smith Report, the David Report contains no factual analysis or even an opinion as to whether the product at issue, Actonel®, is indeed a commercial success. Instead, Dr. David, an economist, merely makes a legal argument about the evidentiary weight that should be accorded to evidence of commercial success in patent litigation. Put simply, the David Report does not rebut a single fact or opinion set forth in any of P&G's expert reports. The David Report's new arguments on the same subject matter covered by Teva's initial expert report are therefore nothing more than a poorly masked attempt to create an extremely belated and unauthorized third round of expert reports. Accordingly, the Court should strike the David Report and preclude Dr. David's testimony at trial.

III. CONCLUSION

On the bases described above, the David Report is improper and untimely. Dr. David is unqualified to render the late-submitted legal opinions that are contained in his report, and those legal opinions are inadmissible under the Federal Rules of Evidence. For these reasons, P&G respectfully requests that this Court strike the David Report and preclude Dr. David or any other Teva expert from testifying about the topics addressed in the David Report at any deposition, hearing, or trial in this matter.

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Dated: June 19, 2006

CERTIFICATION PURSUANT TO
DISTRICT OF DELAWARE LOCAL RULE 7.1.1

Counsel for Plaintiff has consulted with counsel for Defendant pursuant to District of Delaware Local Rule 7.1.1 and has determined that Defendant is opposed to the relief sought in the attached motion.

Steven J. Fineman (#4025)

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ORDER

WHEREAS, Plaintiff The Procter & Gamble Company having moved to strike the Expert Report of Jesse David, Ph.D. ("Motion");

WHEREAS, the Court having considered the arguments in support of and in opposition to the Motion, and good cause having been shown for the relief sought in the Motion;

IT IS HEREBY ORDERED this _____ day of _____, 2006 that Plaintiff's Motion is GRANTED and Dr. David or any other Teva expert is precluded from testifying about the topics addressed in the Expert Report of Jesse David, Ph.D. at any deposition, hearing, or trial in this matter.

SO ORDERED this _____ day of _____, 2006.

_____
United States District Judge

CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2005 true and correct copies of the foregoing were caused to be served on counsel of record at the following addresses as indicated.

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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on August 9, 2006, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

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I hereby certify that on August 9, 2006, I have sent by Federal Express, the foregoing document to the following non-registered participants:

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